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(56) Documents Cited

US 4250882 A

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UK CL (Edition T) **A5R**

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(54) Abstract Title

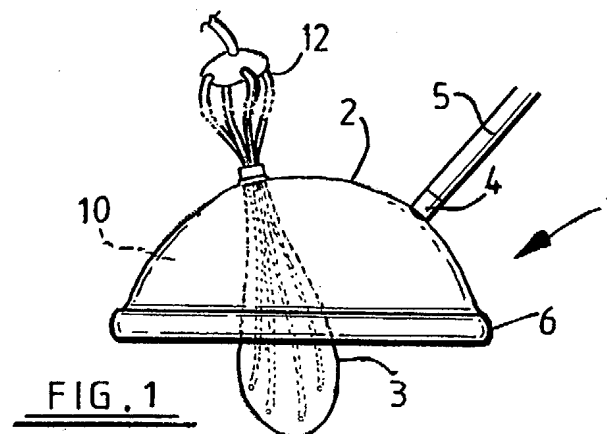
Wound irrigation/suction device

(57) A fluid transfer device 1 for effecting transfer of a fluid to or from the cavity (16) of a wound comprises a reduced pressure applicator 2 having a chamber 10 for location over the wound and being adapted to maintain a reduced pressure in the cavity (16) thereof, the applicator 2 having an aperture (40) by means of which the reduced pressure is applied to the chamber 10;

an inflatable pouch 3 mounted on the applicator 2 and provided at least partly in said chamber 10; and

at least one fluid transfer conduit 12 having an end region carried by the pouch 3 for transferring fluid to or from the cavity (16).

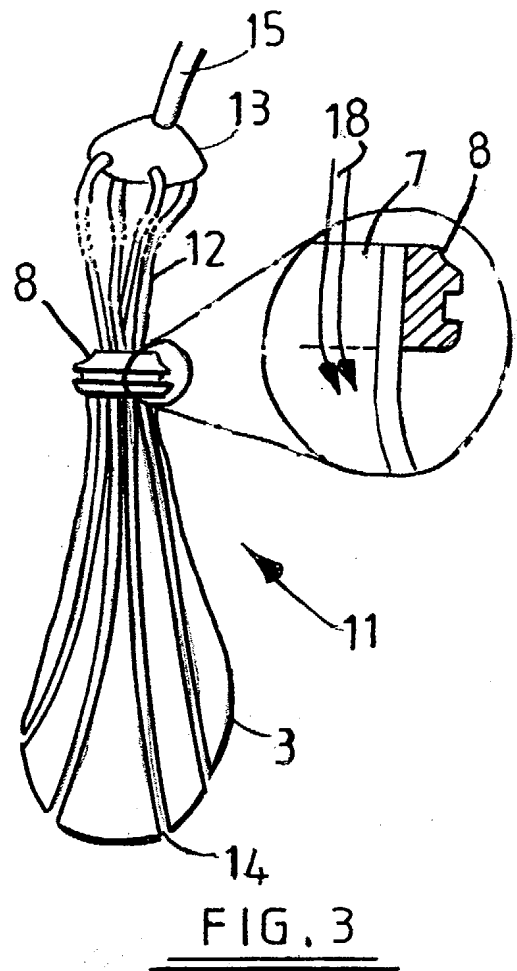
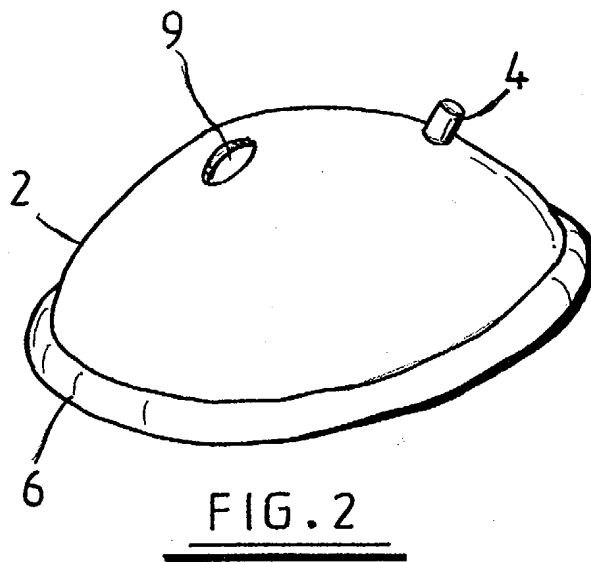
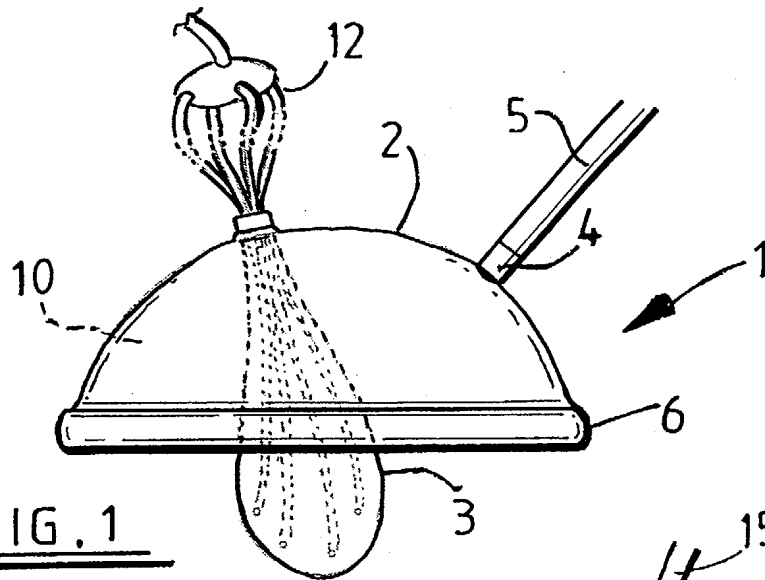
The applicator may be in the form of a rigid cup, when a source of suction is applied the inflatable pouch will expand and fill the wound cavity. The fluid transfer conduits, once in contact with the wound surface will remove exudate or add disinfectant.

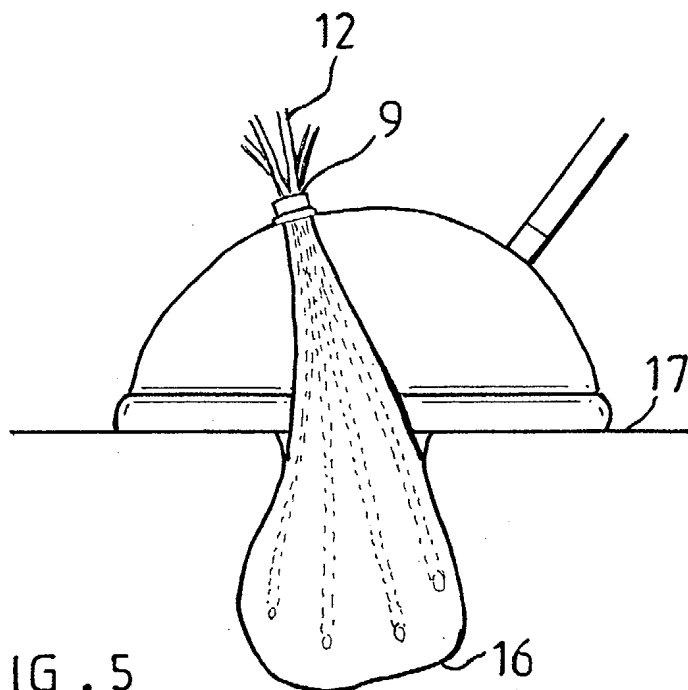
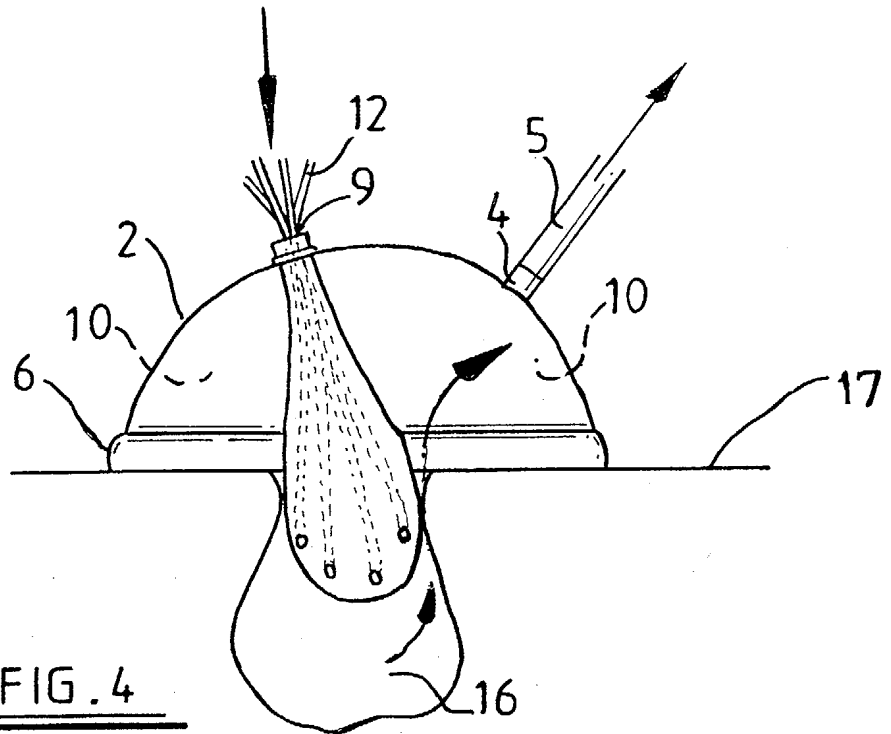


At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

This print takes account of replacement documents submitted after the date of filing to enable the application to comply with the formal requirements of the Patents Rules 1995

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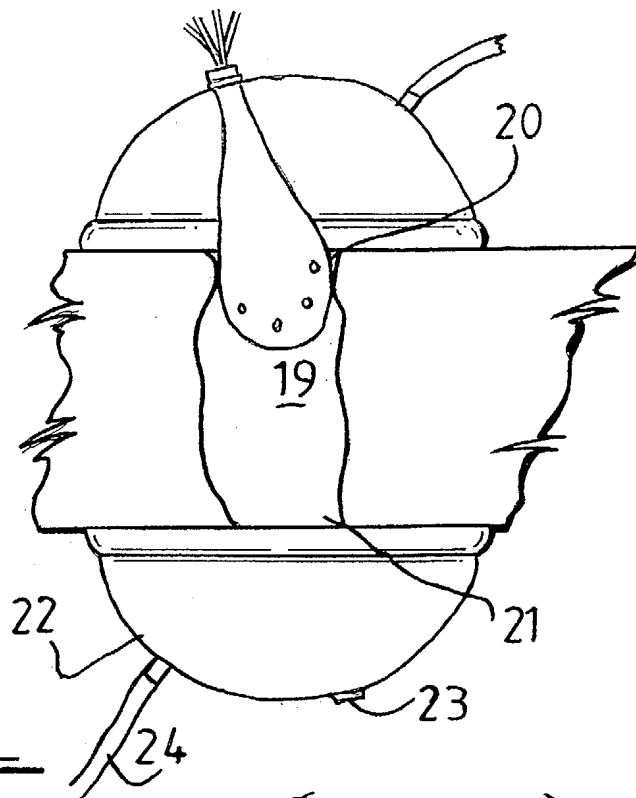


FIG. 6

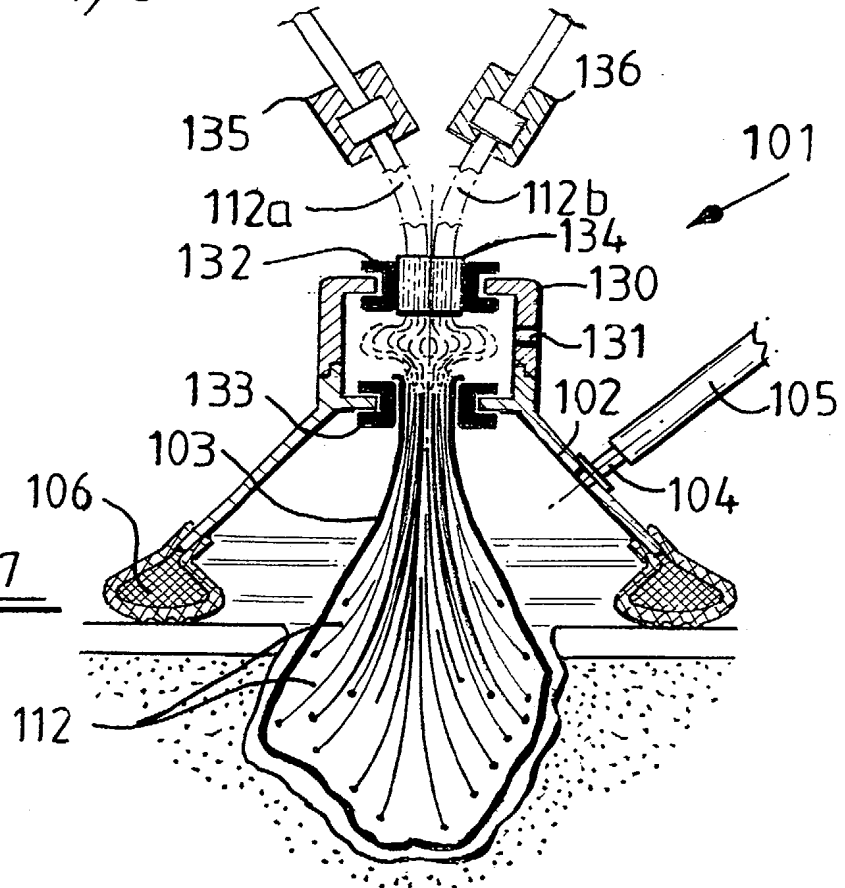


FIG. 7

FLUID TRANSFER DEVICE

The present invention relates to a fluid transfer device intended for use in the treatment of wounds, particularly but not exclusively dermal ulcers.

A dermal ulcer is an area of tissue that has cavitated due to the action of bacteria. Dermal ulcers can range from lesions to bottle-shaped wounds with a small opening and larger cavity or may even be a tunnelled-wound that transects a tissue member.

The internal surface of the cavity of a dermal ulcer is saturated with infected fluids and particulates. These combine with a reduced blood supply, due to collapse and blockage of capillaries, to promote fast necrosis of the tissue. This prevents natural healing of the ulcer and its size grows.

The most commonly used therapy for the treatment of dermal ulcers involves the use of compression bandages but these suffer from the disadvantage that they need to be worn for protracted periods of time during which they may significantly impair function and movement of the affected area to which the bandage has been applied.

A further treatment involves the use of surgery which aims to close the wound using skin grafting. In this case, a surgeon takes a graft from a donor site on the patient and transplants the normal tissue onto the site of the ulcer. This procedure aims to lessen internal infection allowing natural closure but rarely works well. Furthermore surgery is traumatic for the patient and costly in terms of the surgeons time.

It is also known to position a foam insert in the ulcer cavity for the purpose of absorbing exudate but such inserts require frequent replacement, provide a bed for infection, and are distressing for the patient.

It is therefore an object of the present invention to obviate or mitigate the abovementioned disadvantages.

According to the present invention there is provided a fluid transfer device for effecting transfer of a fluid to or from the cavity of a wound, the device comprising

a reduced pressure applicator having a chamber for location over the wound and being adapted to maintain an applied reduced pressure in the cavity thereof, said applicator having an aperture by means of which the reduced pressure is applied to the chamber,

an inflatable pouch mounted in the applicator and provided at least partly in said chamber; and

at least one fluid transfer conduit having an end carried by the pouch and communicating with said chamber for transferring fluid to or from the cavity.

In use of the device, the applicator is positioned over the wound, which may for example be a leg ulcer, and a reduced pressure is applied to the interior chamber of the applicator and thus also to the wound cavity. Additionally, the pouch is caused to inflate so as generally to adopt the same configuration as the wound cavity. The inflation of the pouch causes the (open) ends of the tubes to be positioned adjacent the interior wall of the wound cavity. Fluid (e.g. wound exudate) may be drained from the cavity by applying suction to the fluid transfer conduit(s). Alternatively a fluid (e.g. a disinfectant) may be supplied along the fluid transfer conduit(s) into the cavity for treatment of the wound. The application of reduced pressure to the interior of the cavity has a therapeutic benefit in that it assists in closure of the opening of the wound.

It will thus be appreciated that the invention provides a simple and effective means for ensuring fluid transfer to or from a wound.

In a preferred embodiment of the invention, inflation of the pouch is by means of the interior of the pouch being in communication with ambient air external to the chamber. In this case, the reduction in pressure (below atmospheric) in the wound cavity causes ambient air to be drawn into the pouch to equalise pressures, resulting in inflation of the pouch. This embodiment of the invention is particularly preferred because the reduced pressure within the applicator serves the dual role of inflating the pouch and providing the therapeutic benefit to which reference has been made above.

In this embodiment, the pouch is preferably in the form of a bag supported at its mouth on the applicator such that the mouth is "open" allowing the interior of the bag to be in communication with the ambient air so as to be inflatable as described above.

In an alternative embodiment, inflation of the pouch may be effected by a pressurised fluid (preferably air) supplied to the interior of the pouch. In this embodiment, the interior of the pouch may be in communication with a chamber which provided on the applicator and which is adapted to be connected to a source of elevated fluid pressure. A device relying on the use of pressurised fluid to inflate the pouch may be required in certain circumstances in which the differential pressure alone between the internal applicator pressure (usually a mild vacuum) and the ambient atmosphere is insufficient to inflate the pouch. However a device relying on pressurised fluid is less preferred due to the additional complexity of the device (e.g. the need to provide the additional chamber) and also the need to provide a source of pressurised fluid (e.g. compressed air).

Preferably the applicator is in the form of a rigid cup (e.g. generally hemispherical) which may for example be of polyethylene or other material capable of withstanding the reduced pressure to which the applicator is subjected without collapse. The applicator preferably has a conformable edge for ensuring a generally airtight seal between the applicator and the patient's skin (around the wound) to which it is applied. This conformable edge is preferably provided by a gel-filled skirt extending around the peripheral edge of the applicator.

Preferably the pouch extends (in its uninflated condition) beyond but within the circumference of the edge of the applicator that is intended to contact the patients' skin.

Preferably a plurality of fluid transfer conduits are provided. Preferably the or each transfer conduit is a fine-bore tube and preferably also the or each fine-bore tube extends from externally of the applicator into the pouch and is fixed at its end to the interior wall of the pouch in register with a respective aperture provided therein. There may, for example, be 1 to 10 apertures per square centimetre over that region of the pouch in which the apertures are provided.

Preferably excess lengths of the fluid transfer tubes are provided (e.g. in coiled form) which may be "taken-up" during inflation of the pouch so as to prevent the tubes from "holding back" inflation of the pouch.

If desired, certain of the tubes may be used exclusively for drainage of fluid from the cavity and the other tubes used exclusively for purging or flushing operations.

The material of the pouch is preferably elastomeric and is conveniently latex although other materials can be used.

The invention will be further described, by way of example only, with reference to the accompanying drawings, in which:

Fig 1 schematically illustrates a first embodiment of fluid transfer device in accordance with the invention for the treatment of ulcers;

Fig 2 is a perspective view of the cup of the device shown in Fig 1;

Fig 3 illustrates the inflatable pouch of the device shown in Fig 1;

Fig 4 illustrates the device of Fig 1 located on an ulcer but prior to inflation of the pouch;

Fig 5 illustrates the device of Fig 1 with the pouch inflated for the purposes of effecting drainage of the ulcer;

Fig 6 illustrates treatment of an ulcer that has transected a tissue member; and

Fig 7 illustrates a second embodiment of fluid transfer device in accordance with the invention

Referring to Fig 1, the illustrated fluid transfer device 1 comprises a generally hemispherical cup 2 on which is supported an inflatable, somewhat pear-shaped pouch 3 and which is further provided with a port 4 to which is attached an air/suction line 5. Furthermore, the mouth of the cup 2 has a soft-walled, sealing skirt 6 filled with a gel (e.g. silicone gel) or comprising a similarly deformable material.

Referring now to Fig 3, it will be seen that the pouch 3 has a mouth 7 supported on the inner annular surface of a grommet 8 so that mouth 7 of the pouch is open to the atmosphere. In the assembled device the grommet 8 locates in an aperture 9 provided adjacent the crown of the cup 2 (see Fig 2) so that the pouch 3 extends downwardly through the interior chamber 10 of the cup 2 and beyond the sealing skirt 6. With the grommet located in the aperture 9, the mouth 7 of the pouch remains open to atmosphere.

The pouch is provided with a fluid transfer assembly 11 comprising a plurality of fine-bore tubes 12 (see Fig 3) which are mounted, at one of their ends, on a manifold arrangement 13 provided externally of the pouch 3 and which extend therefrom downwardly through the open mouth 7 of the pouch 3 into the interior thereof. Within the pouch 3, the fine-bore tubes 12 extend to the lower or outer region thereof at which there are formed, in the walls of the pouch 3, a plurality of apertures 14 each having a diameter which is the same as that of the fine-bore tubes 12. At their lower ends, the fine-bore tubes each communicate with the exterior of the pouch via a respective aperture 14 and are located in position by virtue of being bonded to the pouch.

The illustrated arrangement of pouch 3 and fine-bore tubes 13 can be prepared by a dipping process (or otherwise) using a former which has the same general size and shape as the uninflated pouch 3 and which further has projections for providing the fine apertures 11. Prior to dipping, the fine-bore tubes 12 each have one of their ends fitted over a projection. Subsequently the former is dipped in latex or other suitable material which is then allowed to dry/cure. The dried/cured latex is then stripped from the former and turned inside out so as to produce the arrangement of pouch 3 and fine-bore tubes 12 as illustrated in the drawings.

Within the manifold, the upper ends of the fine-bore tubes 12 are each in communication with a main fluid supply or discharge tube 15.

Reference is now made to Figs 4 and 5 which illustrate use of the device for effecting drainage of an ulcer. More specifically, Fig 4 schematically depicts ulcerated tissue in which the ulcer (e.g. a leg ulcer) is shown as a bottle-shaped cavity 16 in a patient's skin 17. To effect drainage of the ulcer, the device is positioned onto the patient's skin 17 with the soft sealing skirt 6 located around the "opening" of the ulcer and with the lower end of the pouch protruding into the top of the ulcer cavity 16. With the device so positioned, the gel filled skirt gives gentle contact on hypersensitive skin and ensures that the skirt 6 provides an air tight seal between itself and the patient's skin, even if such skin is pitted or macerated, since the gel will flow from high to low points and pressures.

With the device positioned as shown in Fig 4, suction is applied to the tube 5 so as to reduce the pressure within the chamber 10 and the cavity 16 of the ulcer.

The effect of this pressure reduction is that ambient air enters the (open) mouth 7 of the pouch (as depicted by arrow 18 in Fig 3) thus causing the pouch to inflate so that its lower region conforms to, and contacts, the interior surface of the ulcer cavity, as depicted in Fig 5.

It will be appreciated that the lower ends of the fine-bore tubes 12 which are carried by the pouch 3 are now in effect in contact with the interior wall of the ulcer cavity 16.

Suction is applied to the tube 15 so that exudate from the cavity 16 is drawn into the lower ends of the fine-bore tubes 12, upwardly therealong and then *via* the manifold 13 and tube 15 so to be drained from the ulcer cavity 16. Furthermore, not only is the cavity drained, but the reduced pressure within the cup 2 draws the edges of the ulcer closer together, promotes tissue migration to the inner surface and increases the blood supply. This achieves rapid wound closure.

As an alternative to drainage, treatment fluids may be supplied *via* the manifold 13 downwardly through the fine-bore tubes 12 so as to exit through the apertures 14. The fluid may for example be a disinfectant fluid applied for the purposes of back-flushing the wound.

Although the device has so far been described with reference to a bottle-shaped wound, the device could equally be used for a shallow surface type ulcer, in which case the pouch 3 would simply inflate within the cup 2 whilst having the same effect as previously described.

The invention may also be applied to the rare case of a tunnelled wound such as depicted by reference numeral 19 in Fig 6. As shown in that Figure, the wound has two openings 20 and 21 to atmosphere. In this case, a device 1 as shown in, and described with reference to Fig 1, is positioned over opening 20. Over the other opening 21 is provided a cup 22 of the same type as illustrated in Fig 2, but having a blanking plug 23 over the aperture 9 and also a suction line 24 attached to the port 4.

In the case of the wound 19 shown in Fig 6, reduced pressure is applied to the interior of both the cup 2 of the device 1 and the cup 22 via their respective suction lines 5 and 24. The device 1 on the opening 20 may be operated in entirely the same manner as described with reference to Figs 4 and 5. The provision of the cups 2 and

22 at each end of the wound 19 ensures that tissue migration is allowed at both ends of the wound.

It would be possible, but less ideal, to seal the opening 21 with a dressing (rather than with the cup 22) but this could impede tissue migration at that side.

Reference is now made to Fig 7 which illustrates a further embodiment of fluid transfer device in accordance with the invention.

The device 101 of Fig 7 is to a certain extent of similar construction to that illustrated in Figs 1-6 and comprises a cup 102 (of generally frusto-conical section) which is associated with an inflatable pouch 103 and which is further provided with a port 104 attached to a suction line 105. The cup 102 has a compliant skirt 106 and is associated with fine bore tubes 112 which extend within the pouch 103 and which open at the surface thereof.

The device 101 has facility for assisting inflation of the pouch 103 by means of air at elevated pressure for certain circumstances in which inflation of the pouch 103 by atmospheric pressure air may not be possible. To this end, the device 101 is provided (in the top of cup 102) with a chamber 130 connected *via* a port 131 source (not shown) air elevated pressure and the interior of pouch 103 is in communication with the chamber 130. In more detail, chamber 130 has upper and lower apertures provided with seal grommets 132 and 133 respectively and the exterior of the neck of pouch 103 is bonded to grommet 133, thus providing the aforementioned communication between chamber 130 and the interior pouch 103.

At the upper end of chamber 130, the tubes 112 are supported in a body 134 which is seemingly located in the upper seal grommet 132.

Externally of chamber 130 the tubes 112 are split into two "bundles" 112a and 112b which are associated with respective manifold grommets 135 and 136. The

bundle 112a serves for purging and flushing of the wound cavity Bundle 112b serves for extraction of fluid from the wound cavity.

Internally of chamber 130, excess lengths of the tubes 112 are provided (e.g. coiled or otherwise bundled) such that when the pouch 103 is inflated, the excess length of tubes 112 is taken-up to prevent the tubes 112 holding back inflation of the pouch 103.

Use of the device 101 is similar to that of device 1 described and illustrated in Figs 1-6 with the exception that, in the case of device 101, pressurised air may be supplied through port 131 to effect inflation of the pouch 103.

CLAIMS

1. A fluid transfer device for effecting transfer of a fluid to or from the cavity of a wound, the device comprising

a reduced pressure applicator having a chamber for location over the wound and being adapted to maintain an applied reduced pressure in the cavity thereof, said applicator having an aperture by means of which the reduced pressure is applied to the chamber,

an inflatable pouch mounted in the applicator and provided at least partly in said chamber; and

at least one fluid transfer conduit having an end region carried by the pouch for transferring fluid to or from the cavity.

2. A device as claimed in claim 1 wherein the interior of said pouch is in communication with ambient air external of the chamber permitting inflation of the pouch into the cavity.

3. A device as claimed in claim 2 wherein the pouch is in the form of a bag supported at its mouth on the applicator such that the interior of the pouch is in communication with ambient air.

4. A device as claimed in claim 1 wherein inflation of the pouch may be effected by a pressurised fluid supplied to the interior of the pouch.

5. A device as claimed in claim 4 wherein the interior of the pouch is in communication with a chamber which is provided on the applicator and which is adapted to be connected to a source of elevated fluid pressure.

6. A device as claimed in any one of claims 1 to 5 wherein a plurality of fluid transfer conduits are provided.

7. A device as claimed in any one of claims 1 to 6 wherein the or each fluid transfer conduit extends from externally of the applicator into the pouch and is fixed at its end to the interior wall of the pouch in register with a respective aperture provided therein.
8. A device as claimed in claim 3 wherein the or each fluid transfer tube extends from externally of the applicator into the pouch via the mouth thereof.
9. A device as claimed in any one of claims 1 to 8 wherein the or each fluid transfer conduit is a fine-bore tube.
10. A device as claimed in any one of claims 1 to 9 wherein the material of the pouch is elastomeric.
11. A device as claimed in claim 10 wherein the pouch is of latex.
12. A device as claimed in any one of claims 1 to 11 wherein the applicator is in the form of a rigid cup.
13. A device as claimed in any one of claims 1 to 12 wherein the applicator has a conformable edge for ensuring a generally airtight seal between the applicator and the patients skin.
14. A device as claimed in claim 13 wherein the conformable edge is provided by a gel-filled skirt extending around the peripheral edge of the applicator that is intended to contact the patient's skin.
15. A fluid transfer device substantially as hereinbefore described with reference to Figs 1 to 6 or Fig 7 of the accompanying drawings.



Application No: GB 0214186.9
Claims searched: 1-15

Examiner: Jason Bellia
Date of search: 9 December 2002

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	-	US 4 250 882 (ADAIR) See column 3 line 65-column 4 line 11 & Figures
A	-	US 3 874 387 (BARBIERI) See column 2 lines 4-24 & Figures

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKCT^T:

A5R

Worldwide search of patent documents classified in the following areas of the IPC⁷:

A61M

The following online and other databases have been used in the preparation of this search report:

EPODOC, PAJ, WPI